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RESEARCH**

APPLICATION NUMBER:

75-147

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 2

2. ANDA # 75-147

3. NAME AND ADDRESS OF APPLICANT
TEVA Pharmaceuticals USA
Attention: Deborah A. Jaskot
650 Cathill Road
Sellersville, PA 18960

4. LEGAL BASIS FOR SUBMISSION
The listed drug is Monoket® Tablets (Isosorbide Mononitrate) 20 mg of Schwarz Pharma.

The applicant certifies that to the best of their knowledge there are no listed patents and no listed exclusivities for Monoket® Tablets, 20 mg.

5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME: N/A

7. NONPROPRIETARY NAME: Isosorbide Mononitrate

8. SUPPLEMENT(s) PROVIDE FOR: N/A

9. AMENDMENTS AND OTHER DATES:

Firm:

Submitted: June 13, 1997
New Correspondence (Bio): August 15, 1997
Amendment: 12/17/97
Amendment: March 11, 1998 Subject of this review
Telephone amendment: November 23, 1998

FDA:

Acknowledgement: July 29, 1997
Deficiency letter: January 21, 1998
Bioequivalency letter: January 11, 1998
Telephone Conversation: November 23, 1998

10. PHARMACOLOGICAL CATEGORY
Vasodilator (Coronary)

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Tablet

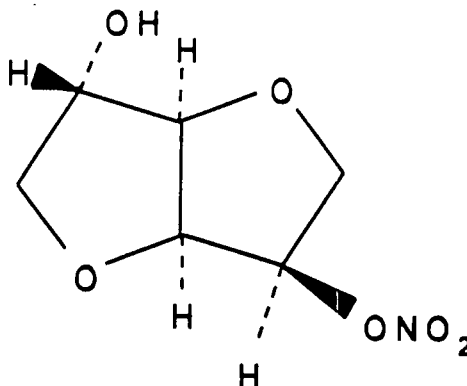
14. POTENCY
20 mg

15. CHEMICAL NAME AND STRUCTURE

Isosorbide

Mononitrate

$C_6H_9NO_6$; M.W. = 191.14



1,4:3,6-Dianhydro-D-glucitol 5-nitrate. CAS [16051-77-7]

16. RECORDS AND REPORTS: N/A

17. COMMENTS

Methods validation is requested on 10-5-98 and still pending. Based on our telephone conversation on Nov-23-98, Teva Pharmaceuticals commits to fully cooperate with FDA district laboratories towards resolving any deficiencies or issues that may be brought forth during the review and validation of the test methods contained in this ANDA.

18. CONCLUSIONS AND RECOMMENDATIONS

The application can be approved. The APPROVAL is pending for method validation.

19. REVIEWER:

Sema Basaran, Ph.D.

DATE COMPLETED:

October 9, 1998/11-23-98

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Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chem Rev 2

10/9/98